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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,495	12/30/2003	Charles R. Roe	BHCS:1007RCE	8734

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
04/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,495	ROE, CHARLES R.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,19-47 and 49-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,19-47 and 49-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 17, 19-47 and 49-57 are pending. Claims 24, 47 and 55 are currently amended.

The response filed **2/27/08** presents remarks and arguments to the office action mailed **1/16/08**. Applicants' request for reconsideration of the rejection of claims in the last office action is acknowledged.

Applicants' arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47 and 49-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims recite obtains mutation from the n-heptanoic acid through an odd carbon". In the specification, para 0076 states a nutritional supplement to a dietary formula comprising low fat and /or reduced long chain fatty acid. From this statement the reduced chain fatty acid can be odd or even.

Applicant is advised to show where in the specification that is recited.

Claim Rejections - 35 USC § 103

Claims 17, 21-25, 34-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchmann et al., US 6,225,347as evidence by Iwama et al., Internal Medicine, vol. 36(9) 1997, 613-617.

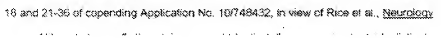
Argument is found persuasive the rejection is withdrawn.

Double Patenting

Applicant's request that the Double Patenting rejection be held in abeyance until it is made permanent is noted but will be maintained in this Office Action and future Office Actions until withdrawn.

Applicant states it is unclear what application 10/748 732 has to do with the claimed invention. It does not. Applicant should take a look again at the office action dated 1/16/08 and will see that the application number is not that which applicant recites. The

office action (a potion has been snagged to show):


Claims 17,19-47 and 49-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-18 and 21-36 of copending Application No. 10/748432, in view of Rice et al., Neurology

Claims 17,19-47 and 49-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 25-27, 37-40, 42-45 and 47-56 of U.S. Patent No. 10/371,385. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

The copending application teaches an infant formula for increasing growth rate comprising seven carbon fatty acids such as n-heptanoic acid and a triglyceride comprising n-heptanoic acid (n-heptanoin). The present application teaches methods of treating a patient with a cardiac disorder comprising administering the instant composition of the copending application. The method claims of the present application are an obvious variation of the claims of the copending application.

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 17, 19-47 and 49-57 and copending application claims 25-27, 38-40, 42-45 and 47-56. As evident by Salzer et al., infants with congenital heart disease have poor weight and length gain (see introduction) and, therefore, need a nutritional supplement. The claimed compositions would have been obvious to one of ordinary skill in the art to use in the treatment of infants with congenital heart disease suffering from poor weight gain.

In view of the foregoing, the copending application claims and the current application claims are obvious variants.

Claims 17,19-47 and 49-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-18 and 21-36 of copending Application No. 10/748432, in view of Rice et al., Neurology

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application teaches an infant formula comprising seven carbon fatty acids such as n-heptanoic acid and a triglyceride comprising n-heptanoic acid (n-heptanoin) in the treatment of a metabolic disorder. The present application teaches methods of use claims containing the instant composition in treating a cardiac disorder. As evident by Rice et al., a metabolic disorder comprises cardiac disorders (see pg. 4 underlined). Thus one of ordinary skill in the art would have been motivated to administer the same composition with a seven carbon chain acid (n-heptanoic acid) to a patient suffering from either a metabolic or cardiac disorder (fatty acid oxidation defects). See pg. 4 as above. Therefore, the copending claims therein are obvious variants of the claims of the instant application.

These are a provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
4/9/08

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614